

STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER:

2. STATE:

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL
SECURITY ACT (MEDICAID)TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

JAN. 4, 2004

5. TYPE OF PLAN MATERIAL (Check One):

☐ NEW STATE PLAN☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION:

42 CFR PART 440

7. FEDERAL BUDGET IMPACT: 12.0

a. FFY 2004 \$(13.5) million

b. FFY 2005 \$(18.0) million (16.5)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 3.1 A&B, Supplement 1, pp 20-
25 of 41; Attachment 4.19-B, p 8.1 of 15.9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION
OR ATTACHMENT (If Applicable):

same pages

10. SUBJECT OF AMENDMENT:

Pharmacy Services: Preferred Drug List for Prior Authorization and State Supplement
Rebates

11. GOVERNOR'S REVIEW (Check One):

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL☒ OTHER, AS SPECIFIED: Secretary, Health and
Human Resources

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME:

Patrick W. Finnerty

14. TITLE:

Director

15. DATE SUBMITTED:

12/2/2003

16. RETURN TO:

Dept. of Medical Assistance Services
600 East Broad St., Suite 1300
Richmond, VA 23219

ATTN: Reg. Coordinator

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

12/15/03

18. DATE APPROVED:

FEB 12 2004

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

1/4/04

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

MARY T. MCSORLEY

22. TITLE: ASSOCIATE REGIONAL ADMINISTRATOR
DIVISION OF MEDICAID & CHILDREN'S HEALTH

23. REMARKS:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of VIRGINIA

NARRATIVE FOR THE AMOUNT, DURATION AND SCOPE OF SERVICES

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

A. Prescribed drugs.

1. Drugs for which Federal Financial Participation is not available, pursuant to the requirements of §1927 of the Social Security Act (OBRA '90 §4401), shall not be covered.
2. Non-legend drugs shall be covered by Medicaid in the following situations:
 - a. Insulin, syringes, and needles for diabetic patients;
 - b. Diabetic test strips for Medicaid recipients under 21 years of age;
 - c. Family planning supplies;
 - d. Designated categories of nonlegend drugs for Medicaid recipients in nursing homes;
 - e. Designated drugs prescribed by a licensed prescriber to be used as less expensive therapeutic alternatives to covered legend drugs.
3. Legend drugs are covered for a maximum of a 34-day supply per prescription per patient with the exception of the drugs or classes of drugs identified in 12VAC30-50-520 (Supplement 5 to Attachment 3.1 A&B). FDA-approved drug therapies and agents for weight loss, when preauthorized, will be covered for recipients who meet the strict disability standards for obesity established by the Social Security Administration in effect on April 7, 1999, and whose condition is certified as life threatening, consistent with the Department of Medical Assistance Services' medical necessity requirements, by the treating physician.
4. Prescriptions for Medicaid recipients for multiple source drugs subject to 42 CFR 447.332 shall be filled with generic drug products unless the physician or other practitioners so licensed and certified to prescribe drugs certifies in his own handwriting "brand necessary" for the prescription to be dispensed as written or unless the drug class is subject to the Preferred Drug List.

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5. New drugs shall be covered pursuant to the Social Security Act of §1927(d) (OBRA '90 §4401).
 6. The number of refills shall be limited pursuant to § 54.1-3411 of the Drug Control Act.
 7. Drug prior authorization.

Definitions. The following words and terms, when used in these regulations, shall have the following meaning, unless the context clearly indicates otherwise:

“Clinical data” means drug monographs as well as any pertinent clinical studies, including peer review literature.

“Complex drug regimen” means treatment or course of therapy that typically includes multiple medications, co-morbidities and or caregivers.

“Department” means the Department of Medical Assistance Services.

“Drug” shall have the same meaning, unless the context otherwise dictates or the Board otherwise provides by regulation, as provided in the Drug Control Act (§54.1-3400 et seq.).

“Emergency supply” means a 72-hour supply of the prescribed medication that is dispensed if the physician is not available to consult with the pharmacist, including after hours, weekends, holidays or other criteria defined by the P & T Committee and DMAS.

“Non-preferred drugs” means those drugs that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Non-preferred drugs may be prescribed but require prior authorization prior to dispensing to the patient.

“Pharmacy and Therapeutics Committee (P&T Committee)” or “Committee” means the Committee formulated to review therapeutic classes, conduct clinical reviews of specific drugs, recommend additions or deletions to the preferred drug list, and perform other functions as required by the Department.

“Preferred drug list (PDL)” means the list of drugs that meet the safety, clinical efficacy, and pricing standards employed by the P&T Committee and adopted by the Department for the Virginia Medicaid fee-for-service program. Most drugs on the PDL may be prescribed and dispensed in the Virginia Medicaid fee-for-service program without prior authorization; however, some drugs as

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recommended by the Pharmacy and Therapeutics Committee may require authorization prior to dispensing to the patient.

“Prior authorization” as it relates to the PDL, means the process of reviewing drugs, which are not on the preferred drug list or other drugs as recommended by the Pharmacy and Therapeutics Committee, to determine if medically justified.

“State supplemental rebate” means any cash rebate that offsets Virginia Medicaid expenditure and that supplements the Federal rebate. State supplemental rebate amounts shall be calculated in accordance with **Virginia Supplemental Rebate Agreement and Addenda**.

“Therapeutic class” means a grouping of medications sharing the same Specific Therapeutic Class Code (GC3) within the Federal Drug Data File published by First Data Bank, Inc.

- a. Medicaid Pharmacy and Therapeutics Committee.
- (1) The Department shall utilize a Pharmacy and Therapeutics Committee (the “P & T Committee”) to assist in the development and ongoing administration of the preferred drug list and other pharmacy program issues. The Committee may adopt bylaws that set out its make up and functioning. A quorum for action of the Committee shall consist of seven members.
 - (2) Vacancies on the Committee shall be filled in the same manner as original appointments. The Department shall appoint individuals for the Committee that assures a cross-section of the physician and pharmacy community.
 - (3) Duties of the Committee. The Committee shall receive and review clinical and pricing data related to the drug classes. The Committee’s medical and pharmacy experts shall make recommendations to DMAS regarding various aspects of the pharmacy program. For the preferred drug list program, the Committee shall select those drugs to be deemed preferred that are safe, clinically effective, as supported by available clinical data, and meet pricing standards. Cost-effectiveness or any pricing standard shall be considered only after a drug is determined to be safe and clinically effective.

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- (4) In formulating its recommendations to the Department, the Committee shall not be deemed to be formulating regulations for the purposes of the Administrative Process Act (§2.2-4000 *et seq.* of the Code of Virginia).
- (5) Pursuant to 42 U.S.C. § 1396r-8(b)(3)(D), information disclosed to the Department or to the Committee by a manufacturer or wholesaler which discloses the identity of a specific manufacturer or wholesaler and the pricing information regarding the drugs by such manufacturer or wholesaler is confidential and shall not be subject to the disclosure requirements of the Virginia Freedom of Information Act (§2.2-3700 *et seq.* of the Code of Virginia).
- (6) Immunity. The members of the Committee and the staff of the Department and the contractor shall be immune, individually and jointly, from civil liability for any act, decision, or omission done or made in performance of their duties pursuant to this subsection while serving as a member of such board, Committee, or staff provided that such act, decision, or omission is not done or made in bad faith or with malicious intent.
- b. Pharmacy prior authorization program. Pursuant to § 1927 of the Act and 42 CFR 440.230, the Department shall require the prior authorization of certain specified legend drugs. For those therapeutic classes of drugs subject to the preferred drug list program, drugs not included in the DMAS preferred drug list shall be subject to prior authorization. The Department also may require prior authorization of other drugs only if recommended by the P&T Committee. Providers who are licensed to prescribe legend drugs shall be required to obtain prior authorization for all non-preferred drugs or other drugs as recommended by the P&T Committee.

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- c. Prior authorization shall consist of prescription review by a licensed pharmacist or pharmacy technician to ensure that all predetermined clinically appropriate criteria, as established by the P & T Committee relative to each therapeutic class, have been met before the prescription may be dispensed. Prior authorization shall be obtained through a call center staffed with appropriate clinicians, or through written or electronic communications (e.g., faxes, mail). Responses by telephone or other telecommunications device within 24 hours of a request for prior authorization shall be provided. The dispensing of a 72-hour emergency supply of the prescribed drug shall be permitted and dispensing fees shall be paid to the pharmacy for such emergency supply.
- d. The preferred drug list program shall include: (i) provisions for an expedited review process of denials of requested prior authorization by the Department; (ii) consumer and provider education, (iii) training and information regarding the preferred drug list both prior to implementation as well as ongoing communications, to include computer and website access to information and multilingual material.
- e. Appeals for denials of prior authorization shall be addressed pursuant to 12 VAC 30-110-10 Part I Client Appeals.
- f. Exclusion of protected groups from pharmacy preferred drug list prior authorization requirements. The following groups of Medicaid eligibles shall be excluded from pharmacy prior authorization requirements: individuals enrolled in hospice care, services through PACE or pre-PACE programs; persons having comprehensive third party insurance coverage; minor children who are the responsibility of the juvenile justice system; and refugees who are not otherwise eligible in a Medicaid covered group.
8. State supplemental rebates. The Department has the authority to seek supplemental rebates from drug manufacturers. The contract regarding supplemental rebates shall exist between the manufacturer and the Commonwealth. Rebate agreements between the Commonwealth and a pharmaceutical manufacturer shall be separate from the federal rebates and in compliance with federal law, §§ 1927(a)(1) and 1927(a)(4) of the Social Security

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Act (Act). All rebates collected on behalf of the Commonwealth shall be collected for the sole benefit of the state share of costs. One hundred percent (100%) of the supplemental rebates collected on behalf of the state shall be remitted to the state. Supplemental drug rebates received by the Commonwealth in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.

9. Coverage of home infusion therapy. This service shall be covered consistent with the limits and requirements set out within home health services (12 VAC 30-50-160). Multiple applications of the same therapy (e.g. two antibiotics on the same day) shall be covered under one service day rate of reimbursement. Multiple applications of different therapies (e.g. chemotherapy, hydration, and pain management on the same day) shall be covered under a full service day rate methodology as provided in pharmacy services reimbursement.

12b. Dentures.

- A. Provided only as a result of EPSDT and subject to medical necessity and preauthorization requirements specified under Dental Services.

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**METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATE-
OTHER TYPES OF CARE**

- b. The cost of the active ingredient or ingredients for chemotherapy, pain management and drug therapies shall be submitted as a separate claim through the pharmacy program, using standard pharmacy format. Payment for this component shall be consistent with the current reimbursement for pharmacy services. Multiple applications of the same therapy shall be reimbursed one service day rate for the pharmacy services. Multiple applications of different therapies shall be reimbursed at 100% of standard pharmacy reimbursement for each active ingredient.
10. Supplemental rebate agreement. Based on the requirements in Section 1927 of the *Act*, the Commonwealth of Virginia has the following policies for the supplemental drug rebate program for Medicaid recipients:
- a. The model supplemental rebate agreement between the Commonwealth and drug manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004, and entitled Virginia Supplemental Drug Rebate Agreement Contract A and Amendment #2 to Contract A has been authorized by CMS.
 - b. The model supplemental rebate agreement between the Commonwealth and drug manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004 and entitled Virginia Supplemental Drug Rebate Agreement Contract B and Amendment #2 to Contract B has been authorized by CMS.
 - c. The model supplemental rebate agreement between the Commonwealth and drug manufacturers for drugs provided to Medicaid recipients, submitted to CMS on February 5, 2004 and entitled Virginia Supplemental Drug Rebate Agreement Contract C, and Amendments #1 and #2 to Contract C has been authorized by CMS.
 - d. Supplemental drug rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.
 - e. Prior authorization requirements found in section 1927(d)(5) of the Social Security Act have been met .

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- f. Non-preferred drugs are those that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Non-preferred drugs will be made available to Medicaid beneficiaries through prior authorization.
 - g. Payment of supplemental rebates may result in a product's inclusion on the PDL.
- D. All reasonable measures will be taken to ascertain the legal liability of third parties to pay for authorized care and services provided to eligible recipients including those measures specified under 42 USC 1396a(a)(25).

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